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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,887	04/06/2001	Charles D. Claude	ACSC-60087	5563

7590 03/23/2004

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EXAMINER

AHMED, SHEEBA

ART UNIT PAPER NUMBER

1773

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

5/1

<b>Office Action Summary</b>	<b>Application No.</b> 09/827,887	<b>Applicant(s)</b> CLAUDE ET AL.	
	<b>Examiner</b> Sheeba Ahmed	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

1. Applicants response filed on December 23, 3003 has been entered in the above-identified application. **Claims 33-41 are pending.**

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33-36, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabreck et al. (US 6,447,920 B1).

Trotta discloses balloon catheters wherein the balloon comprises a pair of first layers made of a flexible material and a second layer positioned between the first layers and comprises a vinylic polymer having functional groups chemically bonded to the first layers **(the first layers disclosed by Trotta correspond to the first and second layers of the claimed invention and the second layer disclosed by Trotta corresponds to the covalently bonded functionality of the claimed invention)**

(Column 2, lines 8-13). The functional groups, which are found on the vinylic polymers, include carboxylic acid **(thus meeting the limitations of claim 36)** (Column 2, lines 29-35). As is conventional, the balloon catheter comprises an inflation lumen **(which is an elongated shaft as seen in Figure 1 and thus meeting the limitations of claim 38)**

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provided for fluid inflation and deflation of the balloon. The first layers may be formed of nylon and the second (bonding) layer may be formed of a modified polyethylene resin having pendant carboxylic acid groups such that a covalent bond may be formed between the second layer and the first (outer) layers through the carboxylic acid groups (Column 4, lines 17-44).

Trotta does not teach that the second layer has a thickness of about 10 to 150 nanometers.

However, Chabreck et al. disclose coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating provided by applying unsaturated hydrophilic macromonomers and initiator radicals and polymerizing said macromonomers on the surface of the bulk material (Column 1, lines 1-55). The coatings may be applied by immersion, dipping spraying, spreading, pouring, or vapor deposition. The coating thickness can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 (*equivalent to 1 nm*) to 100 mm (Column 23, lines 10-60).

Accordingly, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the second layer or the covalently bonded functionality taught by Trotta given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Chabreck et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 (*equivalent to 1 nm*) to 100 microns. Furthermore, the

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determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (*Fed. Cir.* 1985) and also see *MPEP* 2113. In this case, the product (i.e., the balloon catheter) is obvious despite the process limitation of plasma polymerizing the functionalized layer.

3. Claims 33-37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 6,048,620) in view of Chabrecek et al. (US 6,447,920 B1).

Zhong discloses balloon catheters for angioplasty (Column 1, lines 25-26) wherein at least the balloon part is provided with a coating comprising a polymer having organic acid functional groups and a crosslinking agent having functional groups capable of reacting with organic acid groups wherein the coating is applied, dried and then further coated with a hydrophilic polymer having organic acid functional groups such that the hydrophilic polymer becomes bonded to the polymer of the first coating composition through the crosslinking agent (***the balloon part disclosed by Zhong corresponds to the second layer of the claimed invention, the first coating disclosed by Zhong corresponds to the covalently bonded functionality of the claimed invention and the second coating disclosed by Zhong corresponds to the first coating of the claimed invention***) (Column 3, lines 15-30). Examples of organic acid groups include carboxylic acid groups (Column 4, lines 53-56). Examples of the

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first coating composition include acrylic copolymer dispersions (***thus meeting the limitations of claims 36 and 37***) (Column 5, lines 30-33).

Zhong et al. does not teach that their first coating has a thickness of about 10 to 150 nanometers.

However, Chabreck et al. disclose coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating provided by applying unsaturated hydrophilic macromonomers and initiator radicals and polymerizing said macromonomers on the surface of the bulk material (Column 1, lines 1-55). The coatings may be applied by immersion, dipping spraying, spreading, pouring, or vapor deposition. The coating thickness can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 (*equivalent to 1 nm*) to 100 mm (Column 23, lines 10-60).

Accordingly, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the first coating or the covalently bonded functionality taught by Zhong et al. given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Chabreck et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 (*equivalent to 1 nm*) to 100 microns. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even

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though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (*Fed. Cir.* 1985) and also see *MPEP* 2113. In this case, the product (i.e., the balloon catheter) is obvious despite the process limitation of plasma polymerizing the functionalized layer..

4. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabreck et al. (US 6,447,920 B1) and Zhong (US 6,048,620).

Trotta and Chabreck et al., as discussed above, do not disclose that the first layer (which corresponds to the first layer of the claimed invention) is made of polytetrafluoroethylene.

However, Zhong teaches that the materials used to make a balloon catheter include polytetrafluoroethylene, nylons, PE, PP, PVC and other resins (Column 8, lines 44-55). Zhong shows that polytetrafluoroethylene and nylon are equivalent structures known in the art. Therefore, because these two resins were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute polytetrafluoroethylene for nylon.

5. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabreck et al. (US 6,447,920 B1) and Okuda et al. (US 6,053,939).

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Trotta and Chabreck et al., as discussed above, do not disclose that the first layer (which corresponds to the first layer of the claimed invention) has a node and fibril microstructure.

However, Okuda et al. teach that a material having a nodes and fibril microstructure has excellent biocompatibility (Column 1, lines 11-19).

Accordingly, it would have been obvious to one having ordinary skill in the art to replace the nylon outer layer disclosed by Trotta with a material having a nodes and fibril microstructure given that Okuda et al. specifically teach that such a microstructure provides excellent biocompatibility.

### ***Response to Arguments***

6. Applicant's arguments filed on December 23, 2003 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 33-36, 38, and 41 under 35 U.S.C. 103(a) as being unpatentable over Trotta (US 5,620,649) in view of Chabreck et al. (US 6,447,920 B1) and the rejection of claims 33-37 and 41 under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 6,048,620) in view of Chabreck et al. (US 6,447,920 B1) *(these rejections form the basis of all other rejections as well)* and submit that there is no suggestion to combine the references. In response, the Examiner would like to point out that that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Chabreck et al. specifically disclose coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating provided by applying unsaturated hydrophilic macromonomers and initiator radicals and polymerizing said macromonomers on the surface of the bulk material wherein the coating thickness can be controlled to obtain specific properties and the thickness can be controlled to be from 0.001 (*equivalent to 1 nm*) to 100 mm. Furthermore, with regards to the argument that there is no motivation to combine the above references to obtain Applicants plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer, the Examiner would like to point out that the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see *MPEP 2113*. In this case, the product (i.e., the balloon catheter) is obvious despite the process limitation of plasma polymerizing the functionalized layer.

### **Conclusion**


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (571)272-

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1504. The examiner can normally be reached on Mondays and Thursdays from 8am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Thibodeau can be reached on (571)272-1516. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheeba Ahmed  
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March 16, 2004